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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,528	08/29/2003	Kristin Monday	KM--001	8870
7590 STEVEN SHATTIL P. O. BOX 17355 BOULDER, CO 80308-0355		06/18/2007	EXAMINER WINSTON, RANDALL O	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 06/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/651,528

Applicant(s)

MONDAY, KRISTIN

Examiner

Randall Winston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1203</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-9 and the election of species of g) Tyrosine in the reply filed on 11/06/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 10-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Claims 1-9 will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite because of the term "glandular agent." The metes and bounds of the above "glandular agent" term cannot be delineated, as the specification fails to set forth the metes and bounds of what is encompassed. Are glandular agents either bovine glandular or bovine ovary. If so, what is a bovine glandular? Clarification is required.

Claim 1 is rendered vague and indefinite because of the term "pituitary extract." The metes and bounds of the above "pituitary extract" term cannot be delineated, as the

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specification fails to set forth the metes and bounds of what is encompassed. What is a pituitary extract? It appears to examiner from his interpretation of the specification that a pituitary extract could be the prolactin protein hormone. Clarification is required.

Claim 1 recites the indefinite term "derivatives." The metes and bounds of the above "derivatives" term cannot be delineated, as the specification fails to set forth the metes and bounds of what is encompassed. Derivatives of kelp could be interpreted a variety of active ingredients. Clarification is required.

All other claims depend directly or indirectly from the rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 USC 112, first paragraph, because one can not extrapolate the teaching of the specification to the claimed invention because there is no guidance on or exemplification in the specification to prepare a composition comprising a glandular agent, a kelp derivative and a pituitary extract to increase breast size in a subject. The specification does not enable any person skilled in the art to which it pertains, or with which is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a composition comprising a glandular agent, a kelp derivative and a pituitary extract to increase breast size in a subject. Applicant's specification, however, failed to provide any guidance or any working examples whereby applicant has prepared a composition comprising a glandular agent, a kelp derivative and a pituitary extract to increase breast size in a subject.

Furthermore, it is noted that the state of the prior art at the time the invention was filed did not recognize a composition comprising a glandular agent, a kelp derivative and a pituitary extract to increase breast size in a subject nor did the state of the prior art at the time the invention was filed did not recognize each individual claimed active ingredient within the claimed composition of increasing breast size in a subject. For example, Civelli et al. teach (US 6383764, see, e.g. entire patent, especially claims), that a prolactin releasing peptides of the pituitary controls absence seizures. Furthermore, Fleischner teaches (US 6503529, see, e.g. column 7 lines 46-53) bladderwrack kelp is used as a dietary supplement to regulate thyroid functions. Thus, the art is silent regarding the efficacy of applicant's composition comprising a glandular

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agent, a kelp derivative and a pituitary extract to increase breast size in a subject.

Therefore, applicant's claimed composition comprising a glandular agent, a kelp derivative and a pituitary extract to increase breast size in a subject is unpredictable in the art.

Thus, per reference to the Wands factors, due to the state of the prior art at the time the invention was filed did not recognize the claimed composition as being used to increase breast size in a subject as taught by Civelli and Fleischer thus rendering the claimed composition as being unpredictable in the art and due to applicant's specification failing to provide any guidance or working examples whereby applicant has prepared a claimed composition used to increase breast size in a subject and due to the large quantity of experimentation necessary to demonstrate the claimed composition as being used to increase breast size in a subject, it would require undue experimentation without a reasonable expectation of success for one of skill in the art to practice the invention commensurate in scope of the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CHRISTOPHER R. TATE
PRIMARY EXAMINER